HEMOCHRON® Jr. *Signature*

Whole Blood Microcoagulation System

SERVICE MANUAL

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1.0 Introduction

The portable, battery-powered HEMOCHRON® Jr. Signature is a microcoagulation instrument designed to perform whole blood coagulation tests using fresh whole blood at the patient's bedside. The instrument is manufactured and quality assured using rigorous standards to evaluate and certify each machine.
Under routine operating conditions, the HEMOCHRON® Jr. Signature micro-coagulation instrument will provide uninterrupted trouble-free service. In the event that service is required, the HEMOCHRON® Jr. Signature microcoagulation instrument can be readily disassembled and reassembled with certain easily replaceable components where necessary. Note that this manual is limited only to the diagnostics and replacement of the battery, pump, LED harness assembly and the membrane switch panel. For a complete listing of hazard and fault messages reference the Operator's Manual. This manual does not cover the diagnostics or replacement of the printed circuit board assembly or cuvette housing due to the requirement of specialized test equipment for calibration purposes. The specialized test equipment is only available at ITC repair facilities.

This manual describes the following procedures:

- Certain fault messages and conditions that can be encountered are listed along with a description of the cause and the manner in which it can be resolved.
- Diagnostic procedures to determine whether service is required and, if it is, what type of service is required
- Details for disassembling the instrument and replacing certain key components
- Details for reassembling the instrument
- Testing procedures to verify that the HEMOCHRON® Jr. Signature microcoagulation instrument can be returned to routine use

2.0 Precautions

Safety precautions that are necessary when servicing the HEMOCHRON® Jr. Signature microcoagulation instrument are summarized below. It is important that these precautions be carefully read and understood.

WARNING: POTENTIAL BIOHAZARDOUS MATERIAL - Samples that are analyzed by the HEMOCHRON® Jr. Signature microcoagulation instrument normally contact only the disposable test cuvettes for this instrument. However, universal safety precautions should be taken when handling and disassembling the instrument, since an undetected spill may have occurred. Before servicing the instrument, it should be cleaned and disinfected using the procedures approved by your laboratory, to avoid spreading contamination to laboratory personnel or equipment. A 10% bleach/water solution is recommended for cleaning.

IMPORTANT: Do not use organic solvents or strong cleaning solutions as they may damage the HEMOCHRON® Jr. Signature microcoagulation instrument's plastic components.

IMPORTANT: Only properly qualified personnel using electro-static discharge (ESD) preventive measures should attempt to disassemble and service the HEMOCHRON® Jr. Signature microcoagulation instrument.

IMPORTANT: Before the HEMOCHRON® Jr. Signature microcoagulation instrument is returned to routine use, the system verification procedure that is outlined at the end of this manual must be carried out and acceptable results obtained.

3.0 Replacement Parts List

HJ6003X . . . . . .Pump Assembly
HJ6011X . . . . . .Battery Pack Assembly
FA5059X . . . . . .LED Harness Assembly
See Below . . . . . .Upper Shell Assembly (Top Cover Assembly)

Part Number	Version*
HJ6015X	Hemochron® Jr. Signature
HJ6015X	Hemochron® Jr. Signature International
FA5509X	Hemochron® Jr. II
IL6015X	GEM PCL
HV6015X	SCA 2000

NOTE: The versions listed are covered by this manual.

4.0 Required Tools and Supplies

HEMOCHRON® Jr. Signature Microcoagulation Whole Blood Quality Control Kit
Unused Test Cuvettes
Ohm Meter
Phillips Screwdriver - #1
EQC Cartridge (30 or 300 seconds) Tester

5.0 Troubleshooting

FAULT MESSAGE OR CONDITION	CAUSE	CORRECTIVE ACTION	RELATED PROCEDURE SECTIONS
CHARGE BATTERY	Battery is discharged or fuse blown.	Charge battery for 16 hours. If message persists, check fuses and/or replace battery.	6.1, 7.0, 8.1, 8.2, 9.0, 10.0
SAMPLE TOO LARGE (STL)/ SAMPLE TOO SMALL (STS)	Excess or insufficient sample. Note: 15 ± 1.5 µL of blood is aspirated by the instrument.	Repeat test with new cuvette. If problem persists, a pump may need to be replaced.	6.2, 7.0, 8.3, 8.4, 8.5, 9.0, 10.0
PREMATURE SAMPLE	Sample was detected at front detector before specified time period. May occur if sample is added before pump-priming sequence is complete.	Repeat test with new cuvette. If message persists, a pump may need to be changed. Contact ITC Technical Service.	6.2, 7.0, 8.3, 8.4, 8.5, 9.0, 10.0
DOES NOT ACCEPT KEYPAD ENTRY	Key switch is not functional. permanent or intermittent	Remove and replace membrane switch panel and related assembly.	6.3, 7.1, 9.0, 10.0
CODE	Photo System Error	Remove and replace LED Harness Assembly	8.6, 10.0

6.0 Diagnostic Procedures

6.1 Check Instrument Batteries Pack (HJ6011X) and Fuses

Check the batteries and fuses by determining if the HEMOCHRON® Jr. Signature microcoagulation instrument automatically starts when a cuvette is inserted. For this test, you will need an unused test cuvette.

Procedure:

6.1.1 Before this test, the instrument should be charged for one hour by connecting it to the AC Adapter.

Note: If it is suspected that the batteries have not been deeply discharged and recharged, discharge the batteries by inserting a test cuvette and leaving it in for one day. Then recharge the batteries for 16 hours.

6.1.2 Disconnect the instrument from the AC Adapter.

6.1.3 Insert the test cuvette with the blood reservoir facing up.

6.1.4 If after a series of start-up and warming messages taking about 90 seconds, the messages Add Sample and Press Start are displayed, the batteries and fuses are OK. If the battery/fuse problem persists check the fuse and/or remove and replace the battery per sections 7.0, 8.1, 8.2, 9.0 and 10.0.

6.2 Check Motors and Pumps

Check the motors and pumps by determining if the HEMOCHRON® Jr. Signature microcoagulation instrument automatically draws a specimen into the cuvette. For this test, you will need an unused test cuvette and a HEMOCHRON® Jr. Signature Microcoagulation Whole Blood Quality Control Kit.

Procedure:

6.2.1 Insert the test cuvette with the blood reservoir facing up.

6.2.2 When the messages **Add Sample** and **Press Start** are displayed, fill (using approximately two drops) the center sample well of the test cuvette with whole blood quality control material.

Note: Refer to the HEMOCHRON® Jr. Signature microcoagulation instrument Operator's Manual for details on filling the test cuvette.

6.2.3 Press the **Start** button. If the test proceeds, no problem has occurred. If a problem does occur with the pumps and/or motors, an error message will be displayed.

6.2.4 If an error message is displayed, remove the test cuvette and examine the sample and waste channels. Verify that the waste channel has sample travel that is approximately 75% of the distance between the reservoir and the other end of the cuvette. Also verify that the sample channel contains a sample segment that is approximately one inch long.

If either channel is not filled, the corresponding motors or pumps should be replaced per sections 7.0, 8.3, 8.4, 8.5, 9.0 and 10.0, if inspection of the hoses and seals reveals no leakage.

6.3 Check Switch Keypad (Overlay)

Check the switch keypad by exercising all switches and monitoring for the correct display. For this test you will need an unused test cuvette.
See Figure 1. This procedure is not applicable to Jr.II

Procedure:

6.3.1 Insert the test cuvette with the blood reservoir facing up.
6.3.2 Press “ID” then “1” and then “1” (PID).
6.3.3 Enter “0” through “9” via key switches and verify the entry via the display. Press CANCEL.
6.3.4 Press the “QC” button and the display will indicate “QC SELECTS”, then press the “CANCEL” button to cancel entry.
6.3.5 Press the “DATA BASE” button and the display will indicate “DB SELECTS”, then press the “CANCEL” button to cancel entry.

If any of the key switches/buttons are intermittently or permanently non-functional remove and replace the Keypad Overlay/Top Cover Assembly per sections 7.1, 9.0 and 10.0

7.0 Disassembly Procedures

Disassembly and further testing of the HEMOCHRON® Jr. Signature microcoagulation instrument is described in the following sections.

7.1 Partially Open the Instrument Cover

Procedure:

7.1.1 Position the HEMOCHRON® Jr. Signature microcoagulation instrument so the bottom label is facing you as shown in Figure 2.
7.1.2 Using a Phillips screwdriver, remove the four cover retention screws.
7.1.3 Turn the instrument right side up.
7.1.4 Lift the front of the instrument cover towards you, pivoting the cover like a notepad as shown in Figure 3.
7.1.5 If it is necessary to remove the Keypad Overlay/Top Cover Assembly disconnect J6 from the printed circuit board assembly as shown in Figure 4.

7.2 Release the Pump Tubes

Procedure:

7.2.1 Gently lift the front of the circuit board approximately one inch, until the silicone rubber waste pump tube is accessible.
7.2.2 Grasp the tube fitting where it is held in the recess of the circuit board. Release the tube fitting by sliding it to the left as shown in Figure 3.
7.2.3 Release the second tube fitting in the same manner. The front of the circuit board can now be lifted further.

Important: Do not fully lift the circuit board until you disconnect the battery lead in the next procedure.

7.3 Remove the Battery Lead

Note: If you remove the battery lead, you must reset the time and date for Signature only, not JrII.

Procedure:

7.3.1 Grasp the battery lead connector and remove it from the circuit board. Reference Figure 3.

7.3.2 Lift the circuit board and place it next to the instrument base while it is still connected.

Note: The fuses and battery connections can be inspected and the battery and/or pump assemblies can be replaced without disconnecting the circuit board.

7.4 Remove the Circuit Board Connectors

Note: The circuit board connectors do not have to be removed unless the circuit board must be replaced, except in the case where it is necessary to remove the connectors associated with the LED Harness Assembly. Circuit board replacement can only be done by ITC or authorized repair facility.

8.0 COMPONENT REPLACEMENT

The procedures for checking and replacing components of the HEMOCHRON® Jr. Signature microcoagulation instrument are described in the following sections.

8.1 Examine the Fuses and Battery Pack Connections

Procedure:

8.1.1 Position the circuit board as shown in Figure 3.

8.1.2 Measure the resistance across fuse F1 and fuse F2 to verify that neither is blown. If the resistance across a fuse is greater than 100 ohms, arrange to have the instrument returned and have ITC service personnel replace the circuit board and to have the time and date reset.

8.2 Replace the Battery Pack (If Necessary)

Procedure:

8.2.1 Follow **7.0 DISASSEMBLY PROCEDURES.**

8.2.2 Position the HEMOCHRON® Jr. Signature microcoagulation instrument base so the battery is facing you as shown in Figure 5.

8.2.3 Using a Phillips screwdriver, remove the two battery mounting screws. Remove the battery.

8.2.4 Replace the battery with a new battery.

Note: Dispose of the Nickel-Cadnium (NiCad) battery in accordance with local regulations.

8.2.5 Reassemble instrument per section 9.

8.2.6 Charge the battery 12 to 18 hours before use.

8.2.7 Reset the time and date for all models except JrII.

8.3 Inspect the Pump Assemblies (If Necessary)

If the sample and waste channels of the test cuvette were not properly filled (see the Diagnostic Procedures section of this manual) but the motors were found to work, the pump assemblies should be inspected.

Procedure:

8.3.1 Position the HEMOCHRON® Jr. Signature microcoagulation instrument base so the battery is facing you as shown in Figure 5.

8.3.2 Using a Phillips screwdriver, remove the screws that secure the two mounting brackets. Remove the mounting brackets but do not remove the pump assemblies.

8.3.3 Carefully visually inspect each pump assembly, seals, and tubes for leaks.

8.4 Replace the Pump Assembly (If Necessary)

Note that the replacement pump assembly is pre-tested and pre-torqued and therefore no adjustment is required.

Procedure:

8.4.1 Remove the mounting brackets (Figure 5).

8.4.2 Disconnect the motor connector from the circuit board.

8.4.3 Disconnect the pump tube from the fitting.

8.4.4 Lift the motor and pump assembly from the housing.

Warning: Do not disassemble the cuvette housing, as it is factory set.

8.4.5 Obtain the new pump assembly and place it in the instrument base.

Warning: Do not disassemble the pump assembly, as it is factory set.

8.4.6 Route the wires from the pump motors through the slots in the instrument base. Make sure that the wires are clear of the pump mounting brackets.

Note: The wires from the waste pump assembly are routed over the body of the sample pump assembly.

8.4.7 Replace the pump mounting brackets. Make sure that the pump motor wires are not crimped by the pump mounting brackets.

8.4.8 Make sure that both pump motor assemblies are free to float in their assembled locations. Be especially careful that the waste pump assembly does not interfere with the battery pack.

8.4.9 Connect the new pump tube to the fitting.

8.4.10 Connect the motor connector to the circuit board as described on the following page.

8.5 Reconnect Leads to the Circuit Board if Necessary

The following procedure is only required if the motor connectors were disconnected from the circuit board.

Procedure:

8.5.1 Connect the motor and battery pack connectors as shown in Figure 3.

8.6 Replace the LED Harness Assembly

8.6.1 Disconnect connector J1.

8.6.2 With a Phillips screwdriver remove the mounting screws of the cuvette housing. Reference Figure 2.

8.6.3 With a Phillips screwdriver remove the mounting screws of the LED Harness circuits boards. Reference Figure 6.

8.6.4 Remove the circuit boards from the cuvette housing.

8.6.5 Install LED Harness circuit boards as shown in Figure 6.

8.6.6 Install mounting screws of the LED Harness Assembly circuit boards and cuvette housing with a Phillips screwdriver.

8.6.7 Connect LED Harness connector J1 as shown in Figure 3.

9.0 REASSEMBLY

The procedure for reassembling the HEMOCHRON® Jr. Signature microcoagulation instrument is described below.

9.1 Verify Mounting and Connection of Components

Procedure:

9.1.1 Check that the battery is secured. See Figure 5.

9.1.2 Check that the pump assemblies are properly mounted. See Figure 5.

9.1.3 Check that the pump mounting brackets are secured.

9.1.4 Check that all of the leads are connected to the circuit board and reconnect the Keypad Overlay/Top Cover Assembly connector J6 to the circuit board if it was removed. See Figure 3.

9.2 Fasten the Pump Tubes to the Circuit Board

Procedure:

9.2.1 Position the circuit board over the instrument base as shown in Figure 3.

9.2.2 Slide the sample tube fitting into the circuit board slot that is nearest you (Figure 3).

9.2.3 Slide the waste tube fitting into the other circuit board slot. Make sure that the tubes are not kinked.

9.2.4 Check that all of the leads are connected to the circuit board and reconnect the Keypad Overlay/Top Cover Assembly connector J6 to the circuit board if it was removed. See Figure 3.

9.3 Connect the Battery Lead

Procedure:

9.3.1 Connect the battery lead to the circuit board. Be sure that the polarity of the battery leads matches the polarity indicated on the circuit board (the red battery lead is positive).

9.4 Secure the Top Cover to the Instrument Base

Procedure:

9.4.1 Turn the instrument over, holding the top cover and instrument base together.

9.4.2 Secure the top cover to the instrument base with the four screws.

9.5 Set the Time and Date (if the Battery Lead was Disconnected)

Procedure:

9.5.1 Press the Cancel button.

9.5.2 While continuing to press the Cancel button, insert a cuvette into the instrument.

9.5.3 Release the Cancel button. The message PRESS START is displayed.

9.5.4 Press the Start button.

9.5.5 Enter the time using the numerical keypad. The time must be entered as four characters using a 24-hour time format. For example, enter 0930 for 9:30 AM and enter 1730 for 5:30 PM.

9.5.6 Press the Enter button. The message DATE xx.yy.zzzz is displayed.

9.5.7 Enter the date using the numerical keypad. The date must be entered as eight characters. (x=month, y=day, and z=year)

9.5.8 Press the Enter button.

10.0 SYSTEM VERIFICATION

Before the HEMOCHRON® Jr. Signature microcoagulation instrument is returned to routine use, the system must be checked to verify proper performance. For this test, you will need an Electronic System Verification Cartridge, three unused test cuvettes, and a HEMOCHRON® Jr. Signature Microcoagulation Whole Blood Quality Control kit.

The procedures for performing the verification are described below.

10.1 Run an Electronic System Verification Test

Procedure:

10.1.1 Obtain an Electronic System Verification Cartridge.

10.1.2 Insert the Electronic System Verification Cartridge into the instrument. **An E-QC...TEST** message should be displayed, and the instrument will begin a series of internal tests.

10.1.3 When the message **PRESS E-QC...START NOW** is displayed, press the **START** button on the cartridge. The remainder of the system test will be carried out.

If the **[E-QC = 30 (or 300) SEC]** message is displayed and no fault messages are displayed after the test is completed, proceed to the next section.

If the proper message is not displayed or a fault message is displayed, refer to the Fault Messages section of this manual.

10.2 Test Whole Blood Controls

Procedure:

10.2.1 Insert the test cuvette with the blood reservoir facing up.

10.2.2 When the messages Add Sample and Press Start are displayed, dispense one drop of whole blood quality control material into the center sample well of the test cuvette.

Note: Refer to the HEMOCHRON® Jr. Signature microcoagulation instrument Operator's Manual for details on filling the test cuvette.

10.2.3 Press the **Start** button. After the test, read the results from the display.

10.2.4 Repeat Steps **1** through **3** two more times, using a new test cuvette for each replicate.

10.2.5 Examine the results that were obtained. If no fault messages were displayed and if the results on the replicates are within the Acceptable Range labeling for the whole blood quality control material, the system performance is acceptable.

If fault messages were displayed, refer to the *Fault Messages* section of this manual.

If results on the replicates are not within the Acceptable Range labeling for the whole blood quality control material, verify the system temperature as outlined in the HEMOCHRON® Jr. Signature microcoagulation instrument *Operator's Manual*. If results are still unacceptable, contact ITC for assistance.

11.0 FIGURES

HEMOCHRON® Jr.
Signature
START
ID
QC
DATA BASE
PRINT
1
2
3
4
5
6
7
8
9
CANCEL
0
ENTER

FIGURE 1

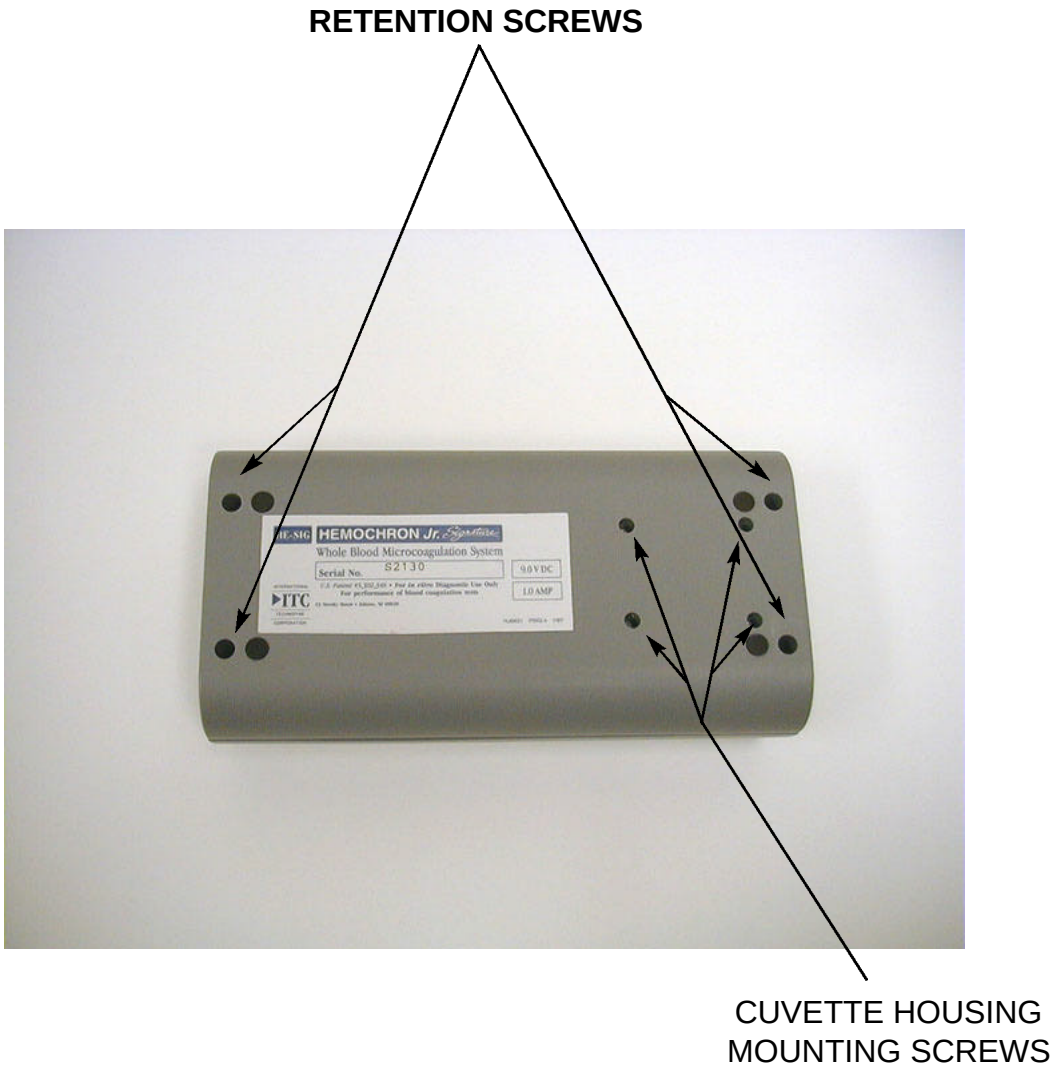

RETENTION SCREWS
HEMOCHRON Jr. Signature
Whole Blood Microcoagulation System
Serial No. S2130
9.0 V DC
1.0 AMP
ITC
CUVETTE HOUSING
MOUNTING SCREWS

FIGURE 2

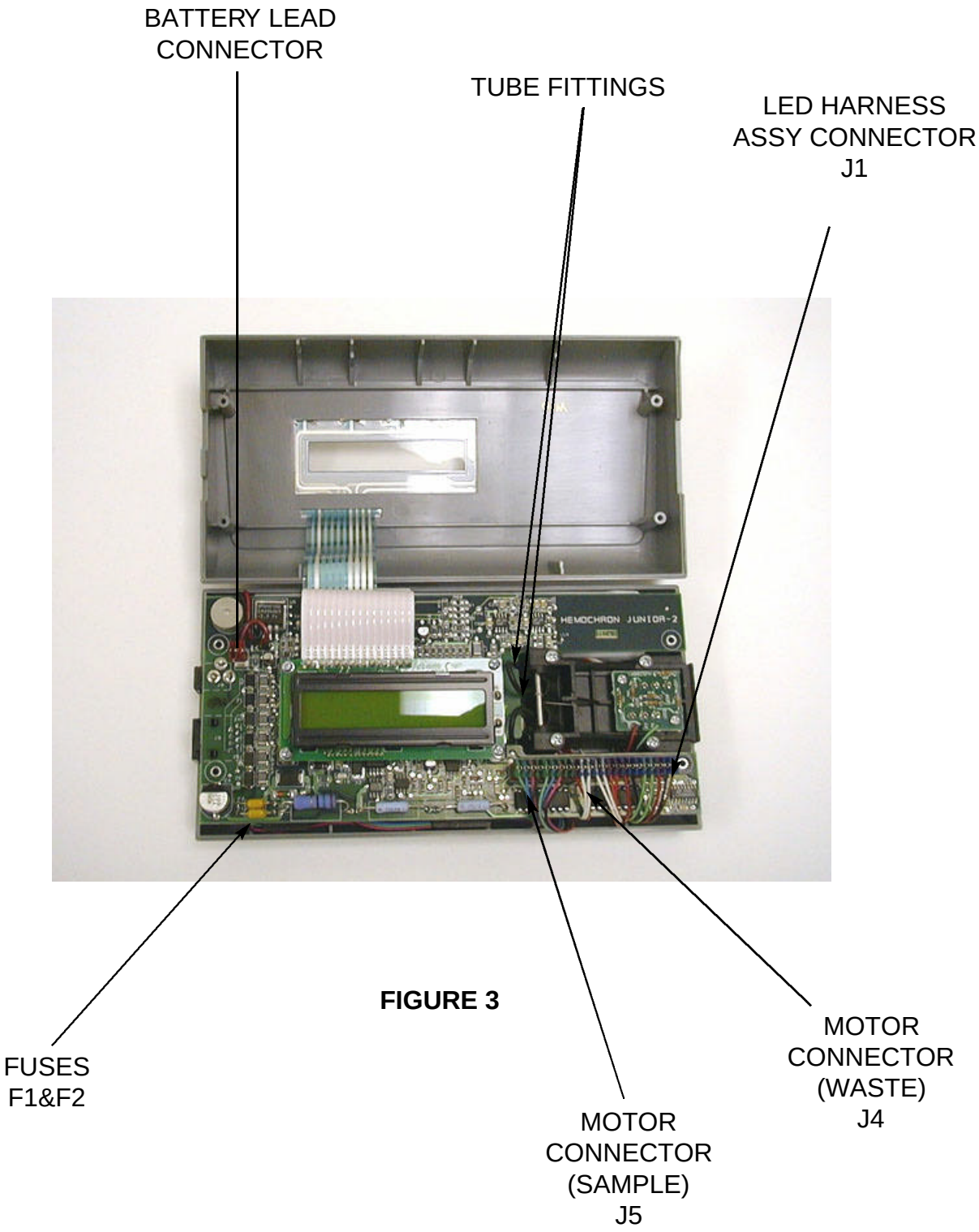

BATTERY LEAD CONNECTOR
TUBE FITTINGS
LED HARNESS ASSY CONNECTOR J1
HEMOCHRON JUNIOR-2
FUSES F1&F2
MOTOR CONNECTOR (SAMPLE) J5
MOTOR CONNECTOR (WASTE) J4

FIGURE 3

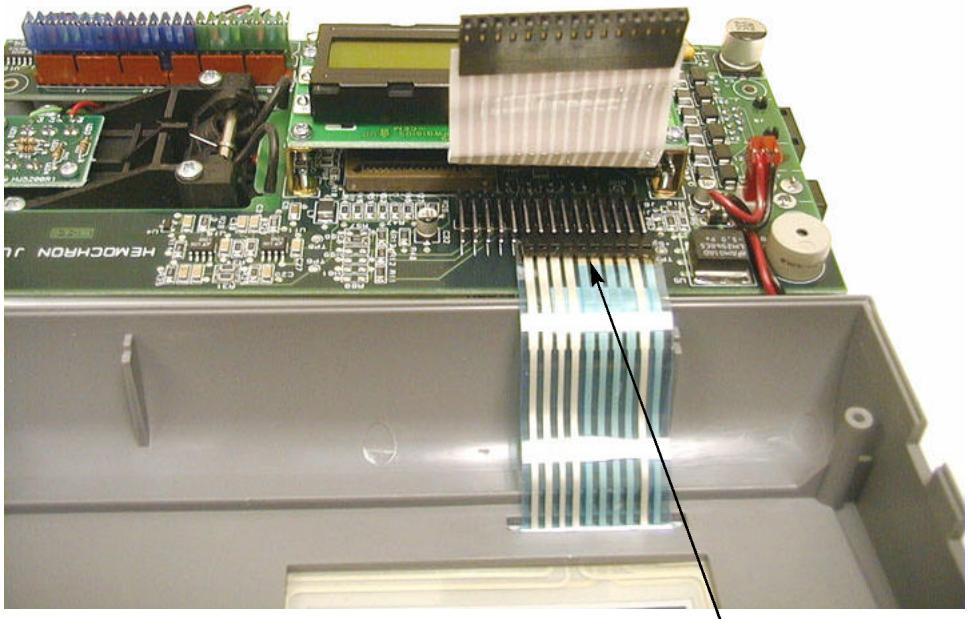


FIGURE 4

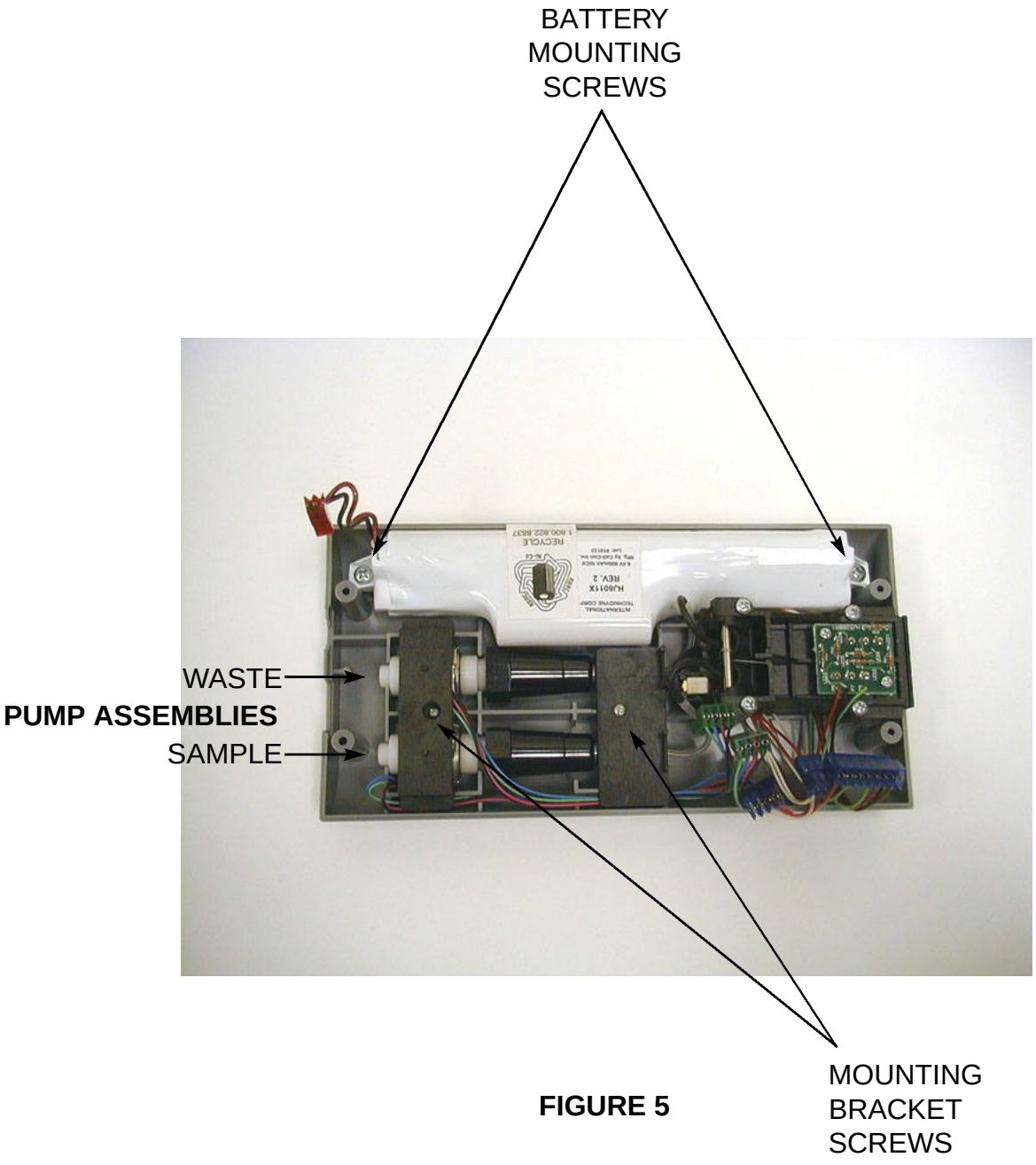

BATTERY
MOUNTING
SCREWS
WASTE
PUMP ASSEMBLIES
SAMPLE
MOUNTING
BRACKET
SCREWS

FIGURE 5

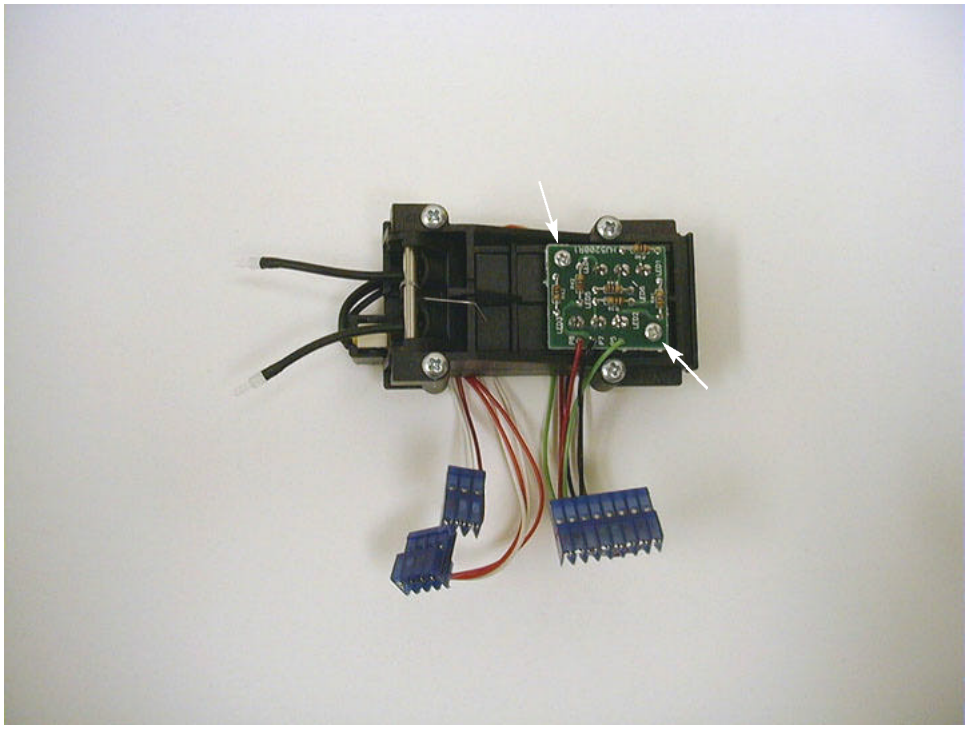
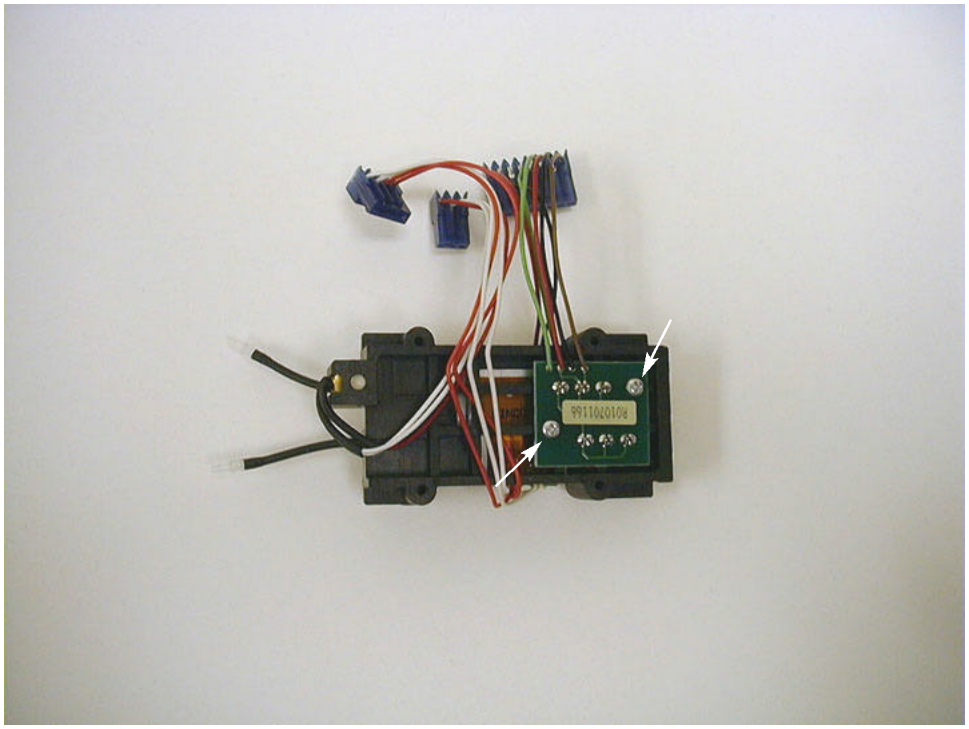


FIGURE 6- LED HARNESS PCB MOUNTING SCREWS



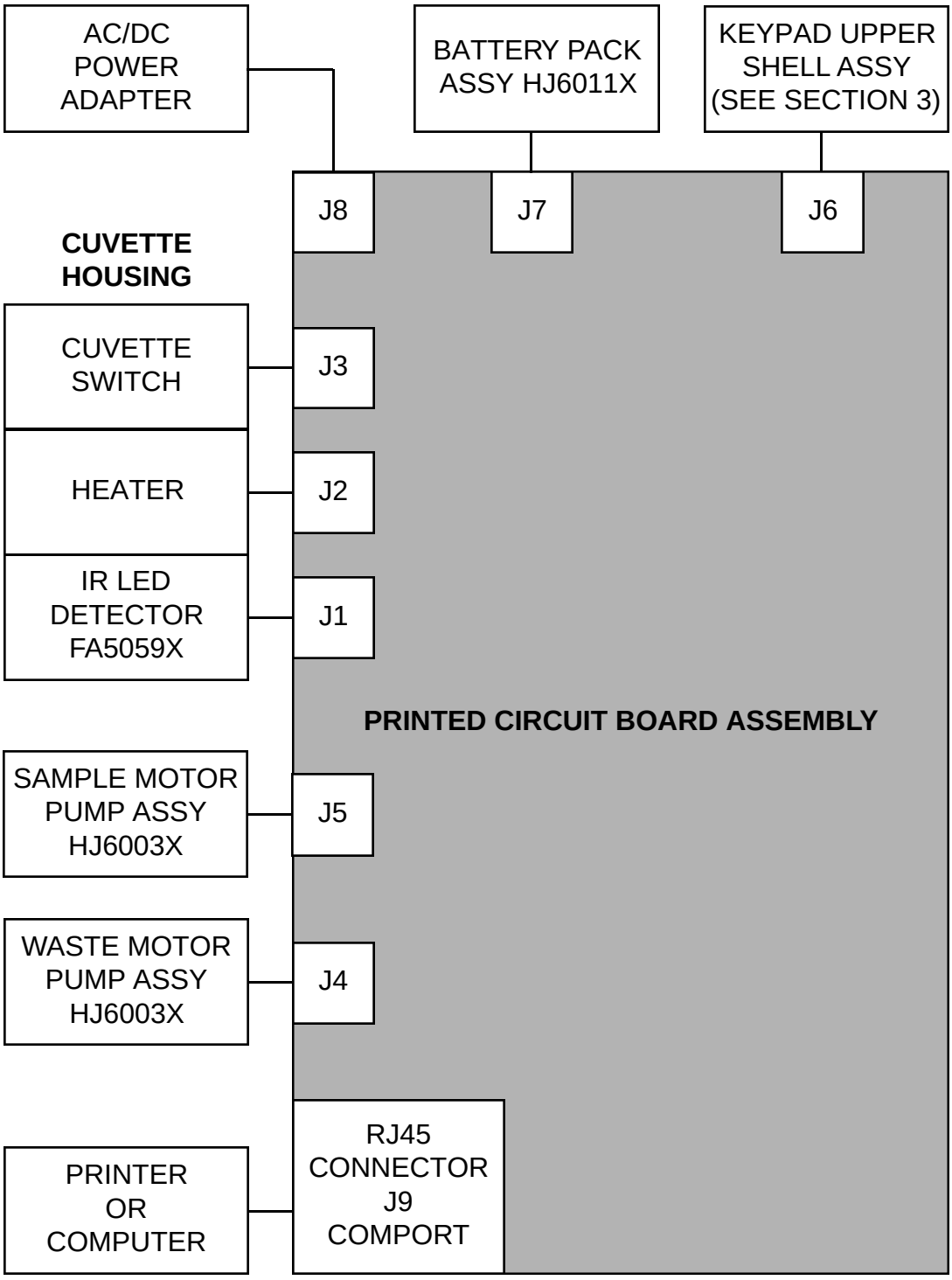


FIGURE 7- FUNCTIONAL SCHEMATIC

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